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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,304	09/05/2003	Andrea M. McPhillips	02972938	8208

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MAYER BROWN LLP
P.O. BOX 2828
CHICAGO, IL 60690

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	

NOTIFICATION DATE	DELIVERY MODE
04/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/656,304	MCPHILLIPS ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 1-10 are pending.

Response to Arguments

In addressing the Objection to the Drawings, Applicants have directed the Examiner to Preliminary Amendment A filed April 29, 2004 which contains amended descriptions of the drawings. As there is no new matter added, the Objection to the Drawings is withdrawn.

Further, Applicants have amended claims 1 and 6-7 to include a range of concentrations for alcohol and glycol that are supported by the specification and the 35 USC 112 rejection is hereby withdrawn.

Applicants present arguments over the 35 USC 103 rejection over Touitou in view of Peart and Vachon. In particular, Applicants argue that claim 1 as now amended overcomes the rejection over Touitou because Touitou requires the presence of a phospholipid while claim 1 is substantially free of a phospholipid. Applicants further argue that Peart discloses that using amounts of ethanol above 20% results in an ineffective formulation.

In response to the above arguments regarding Touitou, it is noted (and will be discussed further below) that this claim limitation is considered new matter. Further, the term "substantially free" means that the presence of some phopholipid may be present. There is no indication of what amount of phospholipid would be present in a case which is "substantially free" of phospholipid. Regarding the teachings of Peart, it is noted that the claim language present reads on amounts of the alcohol at “about 20% to about

70%", of which the term "about" is a relative term that can include amounts below the 20% claimed. Therefore, it is considered that Peart still reads on the pending claim.

Due to Applicants amendments, please see the modified rejections given below.

Claim Rejections – 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, there is no teaching that the composition of the invention is substantially free of a phospholipid. As discussed in the MPEP 2173.05(i), any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no indication as to what the term “substantially free” means. The term "substantially free" means that the composition is not totally free of a particular compound and in the instant case there is no indication as to what minimal amount may be added. Therefore, the claim is considered indefinite.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (U.S. Patent # 5,716,638) in view of Peart et al. (U.S. Patent # 6,509,005) and Vachon et al. (XP-000965573).

Touitou teaches a medical composition comprising ethanol (49%), water (29.4%), and propylene glycol (19.6%) in combination with tetrahydrocannabinol (THC; 7 μci/ml) as the active agent (see Table I), which encompasses claims 1-8.

Touitou fails to teach the dosage form of THC and an aerosol form of the composition.

Peart et al. teach a stable aerosol-dispensable pharmaceutical composition comprising a pharmaceutically effective concentration of delta-9-THC (Column 1, lines 20-27; claims), which is absorbed within seconds and delivered to the brain efficiently. Peart et al. also teach that an organic solvent such as ethanol can assist in solubilizing the delta-9-THC (Column 5, lines 50-52; claims). It is further taught that the optimal size of the respirable dose, or the mass of delta-9-THC in particles with aerodynamic diameters small enough to be delivered to and absorbed by the lungs, is less than 10 μm in size (Column 6, lines 37-48), allowing for effective inhalation. A metered dose inhaler (MDI) is also taught for the aerosol administration of delta-9-THC.

Vachon et al. teach propylene glycol and water (in a ratio of 9:1) as a vehicle for holding THC (4.5 g/100ml) to be administered as an inhaled aerosol with a nebulizer (Materials, Methods and Subjects).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Touitou and Peart and form a stable aerosolable composition with a pharmaceutically effective amount of delta-9-THC because Touitou teaches a composition comprised of ethanol, water, and propylene glycol with delta-9-THC as the active ingredient and Peart teaches an aerosolable composition with a pharmaceutically effective amount of THC. Further it would have been obvious to one skilled in the art at the time the invention was made to further combine the teachings of Vachon who teaches that a vehicle of propylene glycol and water in a ratio of 9:1 is capable of holding up to 4.5 g of THC/100 ml in clear solution,

with Touitou and Peart, because both teach THC as a therapeutic agent and a solvent comprising ethanol.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the composition of Touitou in an aerosolable form of Peart et al. and Vachon et al., for more rapid onset of pharmacological action in the brain after administration of delta-9 THC. One having ordinary skill in the art at the time the invention was made would have been further motivated to employ the composition of Touitou in an aerosolable form of Peart et al. with delta-9 THC particles with aerodynamic diameters less than 10 μm in size to allow for more effective inhalation and absorption by the lungs.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (U.S. Patent # 5,716,638) in view of Peart et al. (U.S. Patent # 6,509,005) and Vachon et al. (XP-000965573) as applied to claims 1-8 above and further in view of LaMastro (U.S. Patent # 5,258,336).

Touitou, Peart et al., and Vachon et al. references are discussed above. Peart teaches administration of a composition via a metered dose inhaler (MDI) and Vachon teaches administration via a nebulizer.

Touitou, Peart et al., and Vachon et al. do not teach a sterile and/or preserved sealed unit-or multi-unit dosage form of delta-9 THC with Type I Amber Glass.

LaMastro et al. teach a Type I amber glass composition that provides a high degree of chemical stability and protection from ultraviolet light for certain pharmaceutical compositions (Column 1, lines 10-13).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Touitou, Peart, and Vachon in further view of LaMastro to house the composition in a sterile and/or preserved sealed unit-or multi-unit dosage form of delta-9 THC in Type I amber glass. One having ordinary skill in the art at the time the invention was made would have been motivated to use Type I amber glass because it provides chemical stability and protection from ultraviolet light for pharmaceutical compositions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617